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REMARKS

Claims 13, 15-17, and 19-34 are now pending in the application. Claims 13-34 stand rejected. Claims 1- 12, 14, and 18 have been canceled.

In accordance with 37 C.F.R. 1.136(a), a three month extension of time is submitted herewith to extend the due date of the response to the Office Action dated June 3, 2003, for the above-identified patent application from September 3, 2003, through and including December 3, 2003. In accordance with 37 C.F.R. 1.17(a)(3), authorization to charge a deposit account in the amount of \$950.00 to cover this extension of time request also is submitted herewith.

The rejection of Claims 13-16, 18, 23 and 30-32 under 35 U.S.C. § 102(b) as being anticipated by Baggiolini et al (5,087,619) is respectfully traversed. Baggiolini et al. teach a method of treating leukemia and basal cell carcinoma in a warm-blooded animal comprising administering an effective amount of a vitamin D analog. The analog is provided to the animal either orally or topically. The oral administrations include capsules and tablets.

Claim 13 recites a dog food comprising a proteinaceous component, a farinaceous component, and a vitamin D analog selected from the group consisting of $1\alpha,25-(\text{OH})_2\text{D}_3$, $1\alpha,25-(\text{OH})_2-16\text{-ene-23-yne- D}_3$, and $1\alpha,25-(\text{OH})_2-22,24\text{-diene-24,26,27-trihomo-D}_3$ and stereoisomers thereof. Baggiolini et al do not describe nor suggest a dog food comprising a proteinaceous component, a farinaceous component, and a vitamin D analog selected from the group consisting of $1\alpha,25-(\text{OH})_2\text{D}_3$, $1\alpha,25-(\text{OH})_2-16\text{-ene-23-yne- D}_3$, and $1\alpha,25-(\text{OH})_2-22,24\text{-diene-24,26,27-trihomo-D}_3$ and stereoisomers thereof. Rather, Baggiolini et al describe providing a vitamin D analog to an animal either topically or orally (via ingestion of capsules or tablets.) Capsules and tablets are not dog food, nor do they comprise a proteinaceous component and a farinaceous component. For the reasons set forth above, Claim 13 is submitted to be patentable over Baggiolini et al.

Claims 14 and 18 have been canceled.

Claims 15-16, 23, and 30-32 depend, directly or indirectly, from independent Claim 13. When the recitations of Claims 15-16, 23, and 30-32 are considered in combination with

the recitations of Claim 13, Applicant submits that dependent Claims 15-16, 23, and 30-32 likewise are patentable over Baggiolini et al.

For the reasons set forth above, Claims 13, 15-16, 23, and 30-32 are submitted to be patentable over Baggiolini et al.

The rejection of Claims 13-23 and 30-32 under 35 U.S.C. § 103(a) as being unpatentable over Baggiolini et al. and Yu et al.(PMID 7756673) is respectfully traversed.

Baggiolini et al is described above. Yu et al. describe experiments conducted with respect to a human cell line and reports examinations of in vitro effects of 1,25 dihydroxy-vitamin D₃ 1,25 (OH)₂D₃ and of two side chain analogs of 1,25(OH)₂D₃ (EB1089 and MC903) on cell growth and parathyroid hormone related peptide (PTHrP) production in immortalized (HPK1A) and neoplastic (HPK1A-ras) keratinocytes.

Claim 13 recites a dog food comprising a proteinaceous component, a farinaceous component, and a vitamin D analog selected from the group consisting of 1 α ,25-(OH)₂D₃, 1 α ,25-(OH)₂-16-ene-23-yne- D₃, and 1 α ,25-(OH)₂-22,24-diene-24,26,27-trihomo-D₃ and stereoisomers thereof. Applicant respectfully submits that Baggiolini et al and Yu et al., alone or in combination neither teach nor suggest a dog food as recited in Claim 13. Baggiolini et al describe providing a vitamin D analog to an animal either topically or orally (via ingestion of capsules or tablets) and does not describe a dog food comprising a proteinaceous component and a farinaceous component. Yu et al describe observing the effects of vitamin D analogs in immortalized and neoplastic keratinocytes. Neither Baggiolini et al nor Yu et al describe a dog food comprising a proteinaceous component and a farinaceous component as recited in Claim 13. For the reasons set forth above, Applicant respectfully requests that the Section 103 rejection of Claim 13 be withdrawn.

Claims 14 and 18 have been canceled.

Claims 15-17, 19-23 and 30-32 depend, directly or indirectly, from independent Claim 13. When the recitations of Claims 15-17, 19-23 and 30-32 are considered in combination with the recitations of Claim 13, Applicant respectfully submits that dependent Claims 15-17, 19-23 and 30-32 likewise are patentable over Baggiolini et al and Yu et al.

Notwithstanding the above, the rejection of Claims 13, 15-17, 19-23 and 30-32 under 35 U.S.C. § 103(a) as being unpatentable over Baggiolini et al and Yu et al is further

traversed on the grounds that the Section 103 rejection of the presently pending claims is not a proper rejection. Obviousness cannot be established by merely suggesting that it would have been obvious to one of ordinary skill in the art to modify Baggiolini et al using the teachings of Yu et al. More specifically, as is well established, obviousness cannot be established by combining the teachings of the cited art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. Specifically, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. Further, it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art.

As the Federal Circuit has recognized, obviousness is not established merely by combining references having different individual elements of pending claims. Ex parte Levengood, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). MPEP 2143.01. Rather, there must be some suggestion, outside of Applicants' disclosure, in the prior art to combine such references, and a reasonable expectation of success must be both found in the prior art, and not based on Applicants' disclosure. In re Vaeck, 20 U.S.P.Q.2d 1436 (Fed. Cir. 1991). In the present case, neither a suggestion or motivation to combine the prior art disclosures, nor any reasonable expectation of success has been shown.

Neither Baggiolini et al nor Yu et al, considered alone or in combination, describe nor suggest the food recited in Claim 13. Baggiolini et al describe providing a vitamin D analog to an animal either topically or orally (via ingestion of capsules or tablets) and does not describe a dog food comprising a proteinaceous component and a farinaceous component. Yu et al. pertains to a human cell line and specifically reports that they have examined the in vitro effects of 1,25 dihydroxy-vitamin D3 [1,25 (OH) ₂D₃] and of two side chain analogs of 1,25 (OH) ₂D₃ (EB1089 and MC903)) on cell growth and PTHRD production in immortalized (HPK1A) and neoplastic (HPK1A-ras) human keratinocytes. Neither Baggiolini et al nor Yu et al describe or suggest a dog food comprising a proteinaceous component, a farinaceous component, and a vitamin D analog. Rather, the present Section 103 rejection appears to be based on a combination of teachings selected from multiple patents in an attempt to arrive at the claimed invention. Specifically, Baggiolini et al is cited

for teaching vitamin D analogs in oral dosage forms such as capsules or tablets and Yu et al is cited for teaching that EB 1089 is known to inhibit cell proliferation and may be useful against neoplastic diseases in human. Since there is no teaching nor suggestion for the combination of Baggiolini et al and Yu et al, the Section 103 rejection appears to be based on a hindsight reconstruction in which isolated disclosures have been picked and chosen in an attempt to deprecate the present invention. Of course, such a combination is impermissible, and for this reason alone, Applicant requests that the Section 103 rejection of Claims 13-23 and 30-32 be withdrawn.

For at least the reasons set forth above, Applicant respectfully requests that the 35 U.S.C. § 103(a) rejection of Claims 13-23 and 30-32 be withdrawn.

The rejection of Claims 24-29, 33, and 34 under 35 U.S.C. § 103(a) as being unpatentable over Baggiolini et al. and Yu et al. in view of Katzung and Hardman et al is respectfully traversed.

Baggiolini et al. and Yu et al are described above.

Katzung describes that hypercalcemia may cause central nervous system depression, including coma and is potentially lethal. Its potential causes (other than thiazide therapy) are hyperparathyroidism and cancer with or without bone metastases. Further Katzung explains that less probable causes are hypervitaminosis D, sarcoidosis, thyrotoxicosis, mil-alkali syndrome, adrenal insufficiency and immobilizations. Katzung does not describe nor suggest pets, dogs, or food for dogs.

Hardman et al describe the use of opioids to treat patients with malignant disease or terminal illness. Hardman does not teach nor suggest that pain is commonly associated with cancer. Hardman appears to be non-analogous art since Hardman does not describe nor suggest pets, dogs, or food for dogs.

Claim 24 depends from Claim 13 which recites a dog food comprising a proteinaceous component, a farinaceous component, and a vitamin D analog selected from the group consisting of $1\alpha,25-(OH)_2D_3$, $1\alpha,25-(OH)_2-16\text{-ene-}23\text{-yne-}D_3$, and $1\alpha,25-(OH)_2-22,24\text{-diene-}24,26,27\text{-trihomo-}D_3$ and stereoisomers thereof. Applicant respectfully submits that Baggiolini et al and Yu et al in view of Katzung and Hardman et al, alone or in combination do not teach or suggest a dog food comprising a proteinaceous component and a

farinaceous component as recited in Claim 13. Baggiolini et al describe providing a vitamin D analog to an animal either topically or orally (via ingestion of capsules or tablets) and does not describe a dog food comprising a proteinaceous component and a farinaceous component. Yu et al describe observing the effects of vitamin D analogs in immortalized and neoplastic keratinocytes. Katzung describes that hypercalcemia may be caused by hypervitaminosis D. Hardman et al describe the use of opioids to treat patients with malignant disease or terminal illness. None of Baggiolini et al, Yu et al, Katzung, and Hardman et al, taken alone or together, teach or suggest a dog food comprising a proteinaceous component and a farinaceous component as recited in Claim 13. For the reasons set forth above, Applicant respectfully requests that the Section 103 rejection of Claim 13 be withdrawn.

Claim 24 depends from Claim 13 and additionally recites that the food further comprises a bone agent, a cytotoxic agent, an immuno response regulating agent, and an anti-inflammatory agent. None of Baggiolini et al, Yu et al, Katzung, and Hardman et al, taken alone or together, teach or suggest a dog food comprising a proteinaceous component and a farinaceous component as recited in Claim 13 and further comprising a bone agent, a cytotoxic agent, an immuno response regulating agent, and an anti-inflammatory agent. For the reasons set forth above, Applicant respectfully requests that the Section 103 rejection of Claim 24 be withdrawn.

Claims 25-29 depend, directly or indirectly, from Claim 24. When the recitations of Claims 25-29 are considered in combination with the recitations of Claim 24, Applicant respectfully submits that dependent Claims 25-29 likewise are patentable over Baggiolini et al and Yu et al in view of Katzung and Hardman et al.

Claim 33 recites a dog food for treating cancer in dogs . . . comprising a proteinaceous component, a farinaceous component, a vitamin D analog, a bone agent, a cytotoxic agent and a anti-inflammatory agent.

None of Baggiolini et al, Yu et al, Katzung, and Hardman et al, taken alone or together, teach or suggest a dog food comprising a proteinaceous component and a farinaceous component as recited in Claim 33. Rather, Baggiolini et al describe providing a vitamin D analog to an animal either topically or orally (via ingestion of capsules or tablets) and does not describe a dog food comprising a proteinaceous component and a farinaceous component. Yu et al describe observed effects of Vitamin D analogs in immortalized and neoplastic keratinocytes. Katzung describes that hypercalcemia may be caused by

hypervitaminosis D. Hardman et al describe the use of opioids to treat patients with malignant disease or terminal illness. None of Baggiolini et al, Yu et al, Katzung, and Hardman et al, taken alone or together, teach or suggest a dog food comprising a proteinaceous component and a farinaceous component as recited in Claim 33. For the reasons set forth above, Applicant respectfully requests that the Section 103 rejection of Claim 33 be withdrawn.

Claim 34 recites a dog food for feeding to a dog, said dog food comprising a proteinaceous component, a farinaceous component, at least one vitamin D analog and at least one of a bone agent, a cytotoxic agent and an anti-inflammatory agent.

None of Baggiolini et al, Yu et al, Katzung, and Hardman et al, taken alone or together, teach or suggest a dog food comprising a proteinaceous component and a farinaceous component as recited in Claim 34. Rather, Baggiolini et al describe providing a vitamin D analog to an animal either topically or orally (via ingestion of capsules or tablets) and does not describe a dog food comprising a proteinaceous component and a farinaceous component. Yu et al describe observed effects of Vitamin D analogs in immortalized and neoplastic keratinocytes. Katzung describes that hypercalcemia may be caused by hypervitaminosis D. Hardman et al describe the use of opioids to treat patients with malignant disease or terminal illness. None of Baggiolini et al, Yu et al, Katzung, and Hardman et al, taken alone or together, teach or suggest a dog food comprising a proteinaceous component and a farinaceous component as recited in Claim 34. For the reasons set forth above, Applicant respectfully requests that the Section 103 rejection of Claim 34 be withdrawn.

Notwithstanding the above, the rejection of Claims 24-29, 33, and 34 under 35 U.S.C. § 103(a) as being unpatentable over Baggiolini et al and Yu et al in view of Katzung and Hardman et al is further traversed on the grounds that the Section 103 rejection of the presently pending claims is not a proper rejection. Obviousness cannot be established by merely suggesting that it would have been obvious to one of ordinary skill in the art to modify Baggiolini et al and Yu et al by using the teachings of Katzung and Hardman et al. More specifically, as is well established, obviousness cannot be established by combining the teachings of the cited art to produce the claimed invention, absent some teaching, suggestion, or incentive supporting the combination. It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the

claimed invention is rendered obvious. Specifically, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. Further, it is impermissible to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art. In the present case, neither a suggestion or motivation to combine the prior art disclosures, nor any reasonable expectation of success has been shown.

None of Baggiolini et al, Yu et al, Katzung and Hardman et al considered alone or in combination, describe or suggest the food recited in Claims 24-29, 33 and 34. Rather, the present Section 103 rejection appears to be based on a combination of teachings selected from multiple patents in an attempt to arrive at the claimed invention. Specifically, Baggiolini et al is cited for teaching vitamin D analogs in oral dosage forms such as capsules or tablets and Yu et al is cited for teaching that EB 1089 is known to inhibit cell proliferation and may be useful against neoplastic diseases in human. Katzung is cited for teaching that hypercalcemia is a consequence of hypervitaminosis D and Hardman et al is cited for teaching that pain is commonly associated with cancer. Since there is no teaching nor suggestion for the combination of Baggiolini et al, Yu et al, Katzung and Hardman et al, the Section 103 rejection appears to be based on a hindsight reconstruction in which isolated disclosures have been picked and chosen in an attempt to deprecate the present invention. Of course, such a combination is impermissible, and for this reason alone, Applicant requests that the Section 103 rejection of Claims 24-29, 33 and 34 be withdrawn.

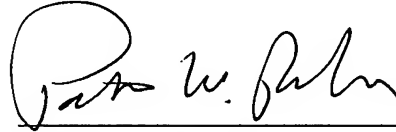
For the reasons set forth above, Applicant respectfully requests that the 35 U.S.C. § 103(a) rejection of Claims 24-29, 33 and 34 be withdrawn.

It is believed that all pending claims are in condition for allowance for at least the reasons set forth above. The recitations in the pending claims are not taught nor suggested in the art cited in the Office Action and thus all claims are deemed to be patentable. The patentability of each dependent claim on its own merits is respectfully requested since each dependent claim is also deemed to recite an additional aspect of the invention requiring consideration or reconsideration, as the case may be.0

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In view of the foregoing amendments and remarks, all claims now active in this application are believed to be in condition for allowance. Reconsideration is requested along with early passage to issue. Favorable action and allowance are respectfully solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Patrick W. Rasche", written over a horizontal line.

Patrick W. Rasche
Reg. No. 37,916
Armstrong Teasdale LLP
One Metropolitan Square, Suite 2600
St. Louis, MO 63012
(314) 342-4136